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EXAMINER

FERNANDEZ, SUSAN EMILY

ART UNIT

PAPER NUMBER

1651

DATE MAILED: 03/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/687,529

Applicant(s)

ABEL ET AL.

Examiner

Susan E. Fernandez

Art Unit

1651

— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 January 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16-20 and 24-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16-20 and 24-37 is/are rejected.
- 7) ☒ Claim(s) 33 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 3/8, 3/16, 4/16, 6/25

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

The preliminary amendment filed January 27, 2005, has been received and entered.

Claims 16-20 and 24-37 are pending.

Election/Restrictions

Applicant's election without traverse of Group IV, claims 16-20 and 24-37 in the reply filed on January 27, 2005, is acknowledged.

Claims 1-15 and 21-23 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on January 27, 2005.

Claims 16-20 and 24-37 are examined on the merits to the extent they read on the elected subject matter.

Priority

It is noted that this application appears to claim subject matter disclosed in prior Application No. PCT/CH02/00209, filed April 15, 2002. However, the application inadvertently references PCT/CH02/00206 in the Application Data Sheet filed October 16, 2003, and in the specification. A reference to the prior application must be inserted as the first sentence(s) of the specification of this application or in an application data sheet (37 CFR 1.76), if applicant intends to rely on the filing date of the prior application under 35 U.S.C. 119(e) or 120. See 37 CFR 1.78(a). For benefit claims under 35 U.S.C. 120, the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of all nonprovisional

applications. Also, the current status of all nonprovisional parent applications referenced should be included.

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence(s) of the specification or in an application data sheet by identifying the prior application by application number (37 CFR 1.78(a)(2) and (a)(5)). If the prior application is a non-provisional application, the specific reference must also include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number.

The status of the parent case should be updated.

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because: The declaration filed July 20, 2004 incorrectly states that the filing date of DE 101 19 036.0 is April 15, 2002, whereas the Application Data Sheet filed October 16, 2003 provides the correct filing date of April 18, 2001. Appropriate correction is required.

Claim Objections

Claim 33 is objected to because of the following informalities: It recites a “**ration** of a length of the diffusion path and a cross-section of the diffusion path” whereas the last paragraph of page 2 discloses a “**ratio** of the length...” Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 16-20 and 24-37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term “geometry” renders claim 16 indefinite. It is not clear what physical properties are encompassed by the “geometry” of a channel. Furthermore, it is unclear how the geometry “limits diffusion”. Which diffusion is limited? For instance, is the diffusion of the analyte limited? Moreover, how is diffusion limited? How much is diffusion limited? Thus claims 16-20 and 24-37 are rejected under 35 U.S.C. 112, second paragraph.

Claim 18 is rendered indefinite because it is not clear what is not allowed to pass through the “impermeable material”. Is the material impermeable to all substances? For examination purposes, material impermeable to certain substances will be considered “impermeable material”. Thus claim 18 is rejected under 35 U.S.C. 112, second paragraph.

The phrases “diffusion-limiting channel” and “diffusion-limiting part” render claims 18 and 20 indefinite, respectively. The phrases are confusing because it is not clear what

characteristics are required for a channel or a part to be considered "diffusing-limiting".

Furthermore, it is not clear which diffusion is limited. For example, is the diffusion of oxygen limited? Thus claims 18 and 20 are rejected under 35 U.S.C. 112, second paragraph.

Claim 19 is rendered indefinite by the phrase "near the surface of the sensor". It is not clear what is encompassed by the term "near". Thus claim 19 is rejected under 35 U.S.C. 112, second paragraph.

Claim 20 is rendered indefinite by the term "part". It is unclear what "part" defines. That is, what "part" is of interest? A part of a channel? Is the "part" planar or three-dimensional? If the "part" is three-dimensional, it is not clear how one compare it with the channel cross-section in order to judge which of the two is larger. Thus claim 20 is rejected under 35 U.S.C. 112, second paragraph.

The term "thin" renders claims 26 and 30 indefinite. It is not clear what is encompassed by the term "thin". The characteristics that would render a membrane "thin" are not defined. Thus claims 26-31 are rejected under 35 U.S.C. 112, second paragraph.

Claim 27 is confusing because it is not clear what is defined by an "area limiting flow". Which flow is limited? Furthermore, it is not clear which membrane is referred to in the claim. Thus claim 27 is rejected under 35 U.S.C. 112, second paragraph.

Claim 31 is indefinite because it is confusing how the enzyme is bound onto or into the wall of a fiber. It is not clear how the hydrophilic wall can be "swollen". Further, it is not clear what would define a "fiber". Thus claim 31 is rejected under 35 U.S.C. 112, second paragraph.

The phrase "diffusion path" renders claim 33 indefinite because it is unclear which "diffusion path" is to be used. Is the "diffusion path" the diffusion path of the analyte? Is the

"diffusion path" in the whole system, the sensor, or a channel? Furthermore, it is not clear what feature of the cross-section of the diffusion path is used in the ratio. Specifically, it is not clear whether a parameter such as the area, circumference, diameter, or radius of the cross-section is used in the ratio that is determined. Thus claim 33 is rejected under 35 U.S.C. 112, second paragraph.

The phrase "effective cross-section" renders claim 35 indefinite. It is not clear what would constitute an "effective cross-section". Furthermore, the phrase "outer concentration gradients" renders claim 35 indefinite. First, it is not clear which substance's concentration is included in the "outer concentration gradients". Additionally, it is unclear what is defined by "outer", which is included in the phrases "outer concentration gradients" and "outer deposit". Is it referring to the region outside the channel entrances? Finally, "diffusion flow" renders claim 35 indefinite because it is not clear which "diffusion flow" is encompassed. Thus claim 35 is rejected under 35 U.S.C. 112, second paragraph.

Claim 37 is rendered indefinite by the term "defined". It is not clear what characteristics are required for a hydrophilic porous substance to be considered "defined". Thus claim 37 is rejected under 35 U.S.C. 112, second paragraph.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 16-20, 24-27, 32-33, and 35-36 are rejected under 35 U.S.C. 102(b) as being anticipated by Janssen et al. (EP 539625).

Janssen et al. discloses a sensor diagrammed on Figure 1. See abstract and column 3, line 34 through column 4, line 11. On Figure 1, the enzyme region is (7), comprising of glucose oxidase in a hydrogel. By definition, a hydrogel contains water. The enzyme region is covered on one side by (8), a material impermeable to the analyte, glucose. Enzyme region (7) is connected to the surface of the sensor by (10), an opening or hole which serves as a channel which leads through impermeable material (8). This channel contains water since its entrance is covered by (9), a water-permeable membrane. Thus water is allowed through (10). Moreover, the portion of (9) above (10) serves as a section of the channel. Therefore, the length of the channel exceeds the thickness of membrane (8). Diffusion of any substance is limited by any "geometry" of a channel because fluid flow is hindered at the walls of any channel.

(9) is defined as being impermeable to high molecular weight components, thus it is impermeable to proteins. Furthermore, (9) is porous because it allows the passage of water and oxygen gas. Therefore, the channel is filled near the surface of the sensor with a porous substance impermeable to proteins. In other words, the region of (9) above (10) serves as a protein-impermeable, hydrophilic layer that the channel passes into on the surface of the sensor.

(12) of Figure 1 demonstrates the diffusion path of glucose. Due to the fact that (8) is impermeable to glucose, the channel forms the only route for transport of glucose to glucose oxidase.

Additionally, there is one portion (or "side") of the enzyme region covered by the anaylte-impermeable, oxygen-permeable membrane (9) where there is no "analyte window" because (10) is not present.

With respect to claim 35, note that increasing the cross-section area of a channel would inherently lead to the result of claim 35.

A holding of anticipation is clearly required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 16-20, 24-30, 32-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Janssen et al. in view of Clark, Jr. (U.S. Pat. 4,680,268).

As discussed above, Janssen et al. discloses a sensor consisting of a enzyme region comprising glucose oxidase in a hydrogel. By definition, a hydrogel contains water. The enzyme region is covered on one side by a material impermeable to the analyte, glucose. The enzyme region is connected to the surface of the sensor by an opening or hole which serves as a channel which leads through impermeable material. This channel contains water since water is allowed through it. The length of the channel exceeds the thickness of a membrane. Diffusion of any substance is limited by any "geometry" of a channel because fluid flow is hindered at the walls of any channel.

The channel is filled near the surface of the sensor with a porous substance which is impermeable to proteins but permeable to water.

Glucose diffuses into the oxidase region. The channel described above forms the only route for transport of glucose to the glucose oxidase layer.

Additionally, there is one portion (or "side") of the enzyme region covered by the analyte-impermeable, oxygen-permeable membrane where there is no "analyte window" because no channels are present.

Increasing the cross-section area of a channel would inherently lead to the result of claim 35.

Janssen et al. does not expressly disclose an inner gas space of the sensor that borders the glucose oxidase layer. Furthermore, it does not disclose that the length of the channel in the sensor is between 0.1 mm and 1 mm.

Clark, Jr. discloses an implantable sensor as described in column 6, lines 14-68, and shown on Figure 1. The sensor includes an enzyme layer (7) which can be glucose oxidase, thus requiring glucose as the analyte (column 10, lines 50-54). The enzyme layer (7) borders an inner gas space (12). The enzyme layer (7) is separated from the inner gas space (12) by a gas-permeable membrane (6a) (column 6, lines 16-20). Membrane (6a) is porous and hydrophilic as it allows passage of gas, including water vapor. Furthermore, inner gas space (12) is in a chamber (6) constructed of gas permeable material allowing for the extraction of oxygen from the sensor's exterior (column 6, lines 53-54, and column 7, lines 29-31). Thus the environment surrounding the chamber serves as an "oxygen reservoir".

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to have included an inner gas space in the Janssen sensor which borders the enzyme layer, wherein the enzyme layer and the gas space are separated by an oxygen-permeable membrane. This inner gas space would have been in communication with an oxygen reservoir. Additionally, the selection of a suitable channel length would have been a routine matter of optimizing a result-effective parameter at the time of applicant's invention.

One of ordinary skill in the art would have been motivated to do this because Clark, Jr. indicates that their invention is "predicated in part upon the discovery that problems heretofore associated with enzyme sensors can be overcome by providing a structure for an ample and/or steady supply of oxygen for enzymatic reaction at the sensor surface" (column 3, lines 43-47). A holding of obviousness is therefore clearly required.

Claims 16-20 and 24-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Janssen et al. and Clark, Jr. as applied to claims 16-20, 24-30, and 32-36 above, and further in view of Gross et al. (WO 96/14026).

As discussed above, Janssen et al. and Clark, Jr. render claims 16-20, 24-30, and 32-36 obvious.

They do not teach a sensor wherein the enzyme is bound to a hollow fiber.

Gross et al. discloses a sensor as described on page 28, lines 15-31, and shown on Figure 2. The Gross sensor comprises a layer of glucose oxidase (27), which borders inner gas spaces (23) and (25). (23) is hollow and in communication with (25), which is connected to a "supply of excess oxygen" (page 28, lines 18-19). This "supply of excess oxygen" serves as an oxygen reservoir. Additionally, communication between enzyme layer (27) and hollow fiber (23) is accomplished through diffusion of the gas through (28). See page 28, lines 26-29. Membrane (28) is porous and hydrophilic since it is permeable to water and oxygen (page 28, lines 20-23).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to have used a hollow fiber as the inner gas space taught in Clark, Jr.

One of ordinary skill in the art would have been motivated to do this because Gross et al. indicates that "the use of a hollow needle (or of some other structure of needle which allows oxygen to reach the location of the enzyme) confers an important advantage over conventional implanted enzyme sensors, as the hollow needle ensures that the rate of reaction is never restricted by a lack of oxygen" (page 13, line 30 through page 14, line 3). A holding of obviousness is therefore clearly required.

Claims 16-20, 24-27, 32-33, and 35-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Janssen et al. in view of von Woedtke et al. (Sensors and Actuators B, 1997, B42(3): 151-156).

As discussed above, Janssen et al. discloses a sensor consisting of an enzyme region comprising glucose oxidase in a hydrogel. By definition, a hydrogel contains water. The enzyme region is covered on one side by a material impermeable to the analyte, glucose. The enzyme region is connected to the surface of the sensor by an opening or hole which serves as a channel which leads through impermeable material. This channel contains water since water is allowed through it. The length of the channel exceeds the thickness of a membrane. Diffusion of any substance is limited by any "geometry" of a channel because fluid flow is hindered at the walls of any channel.

The channel is filled near the surface of the sensor with a porous substance which is impermeable to proteins but permeable to water.

Glucose diffuses into the oxidase region. The channel described above forms the only route for transport of glucose to the glucose oxidase layer.

Additionally, there is one portion (or "side") of the enzyme region covered by the analyte-impermeable, oxygen-permeable membrane where there is no "analyte window" because no channels are present.

Increasing the cross-section area of a channel would inherently lead to the result of claim 35.

Janssen et al. does not expressly disclose that the channel in the sensor leads through a water-impermeable material.

von Woedtkel et al. discloses a sensor comprising of a layer of glucose oxidase covered by a membrane with an analyte door. See Figure 2 on page 152. The membrane is a hydrophobic, gas-permeable membrane, thus it is impermeable to water.

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to have ensured that membrane (8) of the Janssen invention is impermeable to water in addition to glucose

One of ordinary skill in the art would have been motivated to do this because water participates in the catalytic reaction involving glucose oxidase and its substrate, glucose. Furthermore, concentration gradients of oxygen are affected by the fluid flow of water into the enzyme layer. According to Janssen et al., "...the relation between the glucose content in the fluid to be measured and the detection current obtained in the detection electrode is very sensitive to...the concentration or concentration gradient of the oxygen in the sensor itself" (column 2, lines 15-22). Thus, in order to have obtained optimal sensor sensitivity, one would have been motivated to have made modifications that would have eliminated or minimized factors that affect oxygen concentration gradient. A holding of obviousness is therefore clearly required.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan E. Fernandez whose telephone number is (571) 272-3444. The examiner can normally be reached on Mon-Fri 8:30 am - 5:00 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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PRIMARY EXAMINER